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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,585	08/04/2006	David N. Kenigsberg	66654-0001	8734

10291 7590 09/08/2008

RADER, FISHMAN & GRAUER PLLC
39533 WOODWARD AVENUE
SUITE 140
BLOOMFIELD HILLS, MI 48304-0610

EXAMINER	
PORTER, JR, GARY A	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
09/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,585	KENIGSBERG ET AL.	
	Examiner	Art Unit	
	GARY A. PORTER, JR	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/4/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5-7, 22-27, 30-32 and 35-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Taha et al. (US patent 6,564,090).

3. Regarding claims 1 and 7, Taha teaches a method for detecting prolonged myocardial repolarization as an indicator of transmural ischemia or infarction in a mammalian subject (col. 8, lines 28-48), comprising the steps of: obtaining baseline electrocardiogram data derived from the subject (Fig. 2A, step 100); performing an electrocardiogram on the subject after the baseline data was derived from the subject (Fig. 2A, step 104); and comparing the baseline electrocardiogram data with data from the electrocardiogram to determine whether the time interval of myocardial repolarization is increased (Fig. 2C, step 138; col. 8, lines 28-48).

4. In regards to claim 2, Taha teaches comparing QT interval data in the baseline data with the QT interval data from the electrocardiogram (col. 6, lines 1-23; col. 8, lines 28-48).

5. With regards to claim 3, Taha teaches that the comparing step is automated (col. 4, lines 48-63).

6. Regarding claims 5, 23, 26, 31 and 36, Taha teaches that the patient 14 is human (Fig. 1).

7. In regards to claim 6, Taha teaches that the human subject is suspected of having suffered myocardial ischemia after the baseline electrocardiogram data was derived from the subject, as indicated by the severity values assigned to the detected signal (col. 8, lines 28-28).

8. With regards to claims 22, 25, 30 and 35, Taha teaches an electronic apparatus for detecting prolonged myocardial repolarization as an indicator of transmural ischemia or infarction, i.e. myocardium at risk, in a mammalian subject (col. 8, lines 28-48), comprising: means 22 for storing baseline electrocardiogram data derived from the subject (col. 5, lines 14-16); means for performing an electrocardiogram on the subject after the baseline data was derived from the subject (col. 5, lines 17-23); and means for comparing the baseline electrocardiogram data with data from the electrocardiogram to determine whether the time interval of myocardial repolarization is increased (col. 4, lines 48-63; col. 8, lines 28-48).

9. Regarding claims 24, 27, 32 and 37, Taha teaches that the comparing means comprises an algorithm (col. 3, lines 19-21).

10. Claims 7, 9, 25, 29, 30, 34, 35 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Berger (US Patent 5,560,368).

11. Regarding claim 7, Berger teaches a method for detecting prolonged myocardial repolarization in a mammalian subject (Abstract), comprising the steps of: obtaining baseline cardiac electrical data derived from the subject; measuring cardiac electrical activity in the subject after the baseline data was derived from the subject; and comparing the baseline data with data from the measurement of the cardiac electrical activity to determine whether the time interval of myocardial repolarization is increased (col. 9, lines 24-39; Fig. 1).

12. In regards to claims 9, 29, 34 and 39, Berger teaches comparing monophasic action potential data in the baseline data with the monophasic action potential data from the measurement of cardiac electrical activity (col. 9, lines 40-48).

13. With regards to claims 25, 30 and 35, Berger teaches an electronic apparatus for detecting prolonged myocardial repolarization (Abstract), comprising: means 130 for storing baseline electrocardiogram data derived from the subject, i.e. recording digital values in a record (Abstract; Fig. 9; col. 6, lines 59-61); means 90 (Fig. 9; col. 6, lines 36-61) for performing an electrocardiogram on the subject after the baseline data was derived from the subject (Abstract); and means 128 for comparing the baseline electrocardiogram data with data from the electrocardiogram to determine whether the time interval of myocardial repolarization is increased (col. 7, lines 28-32; col. 9, lines 24-39).

14. Claims 10-13 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Starobin et al. (US Patent 6,361,503).

15. Regarding claims 10 and 12, Starobin teaches a method of detecting myocardium at risk or myocardial viability by measurement of changes in myocardial repolarization in a mammalian subject (Abstract), comprising the steps of: performing an electrocardiogram with ECG monitor 30 (Fig. 3) on the subject to obtain baseline electrocardiogram data, i.e. a first ECG recording (Abstract); performing a clinical procedure on the subject, i.e. a stress test with decreasing exercise load (Abstract); monitoring the subject's electrocardiogram during the clinical procedure to obtain electrocardiogram data, i.e. a second ECG reading (Abstract); and comparing the baseline electrocardiogram data with the electrocardiogram data from the clinical procedure to determine whether the time interval of myocardial repolarization is changed during the procedure (Abstract).

16. In regards to claims 11, 13, 17 and 19, Starobin teaches that the subject is a human (col. 4, lines 13-17).

17. Regarding claims 16 and 18, Starobin teaches a method of detecting ischemic preconditioning by measurement of changes in myocardial repolarization in a mammalian subject (Abstract), comprising steps of: initiating an electrocardiogram with ECG 30 (Fig. 3) on the subject and performing a first step of a clinical procedure on the subject, i.e. a stress test with an increasing exercise load (Abstract); capturing first electrocardiogram data from the subject during the time period in which the first step of

the clinical procedure was performed (Abstract); performing one or more additional steps of a clinical procedure on the subject, i.e. a stress test with decreasing exercise load (Abstract); capturing electrocardiogram data, i.e. a second reading, from the one or more additional steps of a clinical procedure (Abstract); and comparing the first electrocardiogram data with electrocardiogram data from the one or more additional steps to determine whether the time interval of myocardial repolarization is changed between the first step of the clinical procedure and any of the subsequent steps (Abstract).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taha et al. (US patent 6,564,090) in view of Morganroth (US Pub. 20030097077).

20. In regards to claim 4, Taha discloses all of the claimed invention except for comparing the ECG's manually. However, Morganroth teaches that the ECG readings can be compared manually in order to obtain a higher degree of accuracy (Section [0003]). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Taha reference to include comparing the ECG's manually, as taught and suggested by Morganroth, for the purpose of obtaining a higher degree of accuracy.

21. Claims 8, 28, 33 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taha et al. (US patent 6,564,090) in view of Millar et al. (*Correlation between refractory periods*...).

22. Regarding claims 8, 28, 33 and 38, Taha discloses comparing durations of QT intervals in order to detect ischemia (col. 8, lines 28-48). Taha does not disclose comparing activation recovery interval data in the baseline data with activation recovery interval data from the measurement of cardiac electrical activity. However, Millar teaches that the activation recovery interval is comparable to the duration of the local action potential and refractory period, i.e. QT interval (Page 1372, col. 2, lines 10-18). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Taha reference to include comparing activation recovery interval data in the baseline data with activation recovery interval data from the measurement of cardiac electrical activity, as taught and suggested by Millar, for the purpose of obtaining an accurate determination of ischemia.

23. Claims 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starobin et al. (US Patent 6,361,503) in view of Millar et al. (*Correlation between refractory periods*...).

24. In regards to claims 14 and 20, Starobin discloses comparing the first electrocardiogram data with electrocardiogram data from the one or more additional steps to determine whether the time interval of myocardial repolarization is changed

between the first step of the clinical procedure and any of the subsequent steps (Abstract). Starobin does not disclose comparing activation recovery interval data in the baseline data with activation recovery interval data from the measurement of cardiac electrical activity. However, Millar teaches that the activation recovery interval is comparable to the duration of the local action potential and refractory period, i.e. QT interval (Page 1372, col. 2, lines 10-18). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Taha reference to include comparing activation recovery interval data in the baseline data with activation recovery interval data from the measurement of cardiac electrical activity, as taught and suggested by Millar, for the purpose of obtaining an accurate determination of ischemia.

25. Claims 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starobin et al. (US Patent 6,361,503) in view of Berger (US Patent 5,560,368).

26. Regarding claims 15 and 21, Starobin discloses obtaining baseline ECG measurements along with subsequent ECG measurements and comparing the morphologies of the measurements in order to determine if the QT interval, i.e. time interval of myocardial repolarization, is changed during a stress test (Abstract). Starobin does not disclose comparing monophasic action potential data in the baseline data with the monophasic potential data from the measurement of cardiac electrical activity. However, Berger teaches that the process for measuring and comparing baseline QT

intervals to subsequent QT intervals can be modified to measure action potential durations defined by monophasic action potentials (col. 9, lines 40-48). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Starobin reference to include comparing monophasic action potential data in the baseline data with the monophasic potential data from the measurement of cardiac electrical activity, as taught and suggested by Berger, for the purpose determining a compromise in the functioning of the heart as evidenced by variations in the ECG morphology.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766